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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,212	10/09/2003	Shigenori Watari		8332

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1797	

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10/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/681,212	WATARI ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/789,625.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-9-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2008 has been entered.

Response to Arguments

2. Applicant's arguments filed August 11, 2008 have been fully considered but they are not persuasive. Applicant admits Laugharm, Jr. et al. do disclose irradiating an acoustic wave to a reaction vessel to perform feedback control relation to an irradiating condition of the acoustic wave. However applicant asserts the controlling of the acoustic wave does not include the position of the wave. The examiner disagrees. Laugharm Jr. el al. discloses:

"The electronic elements, processor, computer, **and/or computer program can in turn control any of a variety of adjustable properties to selectively expose a sample to sonic energy in a given treatment.** These properties can include modulation of the ultrasonic beam in response to a detected effect. Modifiable ultrasonic wave variables can include intensity, duty cycle, pulse pattern, **and spatial location.** Typical input parameters that can trigger an output can include change in level of signal, attainment of critical level, plateauing of effect, and/or rate of change. Typical output actions can include sonic input to sample, such as frequency, intensity, duty cycle;

stopping sample movement or sonic energy; **and/or moving beam within a sample** or to the next sample." (column 7, lines 1-14).

"An ultrasound acoustic field 240 can be generated by the sonic energy source 230, for example, a focused piezoelectric ultrasound transducer, into the fluid bath 600. According to one embodiment, the sonic energy source 230 can be a 70 mm diameter spherically focused transducer having a focal length of 63 mm, which generates an ellipsoidal focal zone approximately 2 mm in diameter and 6 mm in axial length when operated at a frequency of about 1 MHz. **The sonic energy source 230 is positioned so that the focal zone is proximate the surface of the fluid bath 600.** The sonic energy source 230 can be driven by an alternating voltage electrical signal generated electronically by the control system 400.

The positioning system 300 can include at least one motorized linear stage 330 that allows the target to be positioned according to a Cartesian coordinate system. The positioning system 300 may position and move the target 800 relative to the source 230 in three dimensions (x, y, z) and may optionally move either or both of the target 800 and the sonic energy source 230. The positioning system 300 can move target 800 during and as part of the treatment process and between processes, as when multiple samples or devices within the target 800 are to be processed in an automated or high-throughput format. The positioning system 300 may position or move the target 800 in a plane transverse to the focal axis of the sonic energy source 230 (x- and y-axes). The positioning system 300 can position and move the target 800 along the focal axis of the sonic energy source 230 and lift or lower the target 800 from or into the fluid bath 600 (z-axis)." (column 7 lines; 39-68)."

In view of the entire disclosure including the exerts above, the examiner asserts the device can does control the strength and positioning of the bean such that fluid surface (liquid level) is placed within the focal zone of the sonic energy source.

In view of such the examiner maintains the previous rejection of the claims.

Claim Interpretation

3. Applicant has amended the claims, such the reaction vessel containing a specimen and reagent are no longer claimed as elements of the invention. The invention is defined by the elements positively claimed following the transitional phrase "comprising". As such the only required structural elements are an acoustic wave generator and a control means. Therefore, it is not required that a reaction vessel be present. As such, it is only required that the control means be capable of functioning as claimed.

It is unclear if applicant intends to invoke 112 6th paragraph (means plus function) in reference to the control means. If so, it should be noted the function is directed to an unclaimed element (level in the reaction vessel of specimen and reagent).

Furthermore it should be noted that the existence of "a plurality of analysis items" is not a structural element of the device.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 7-16 rejected under 35 U.S.C. 102(e) as being anticipated by Laugharn et al., US 6,948,843.

Laugharn et al. disclose a device and method in which acoustic energy is used to control motion in a fluid. According to one embodiment, the invention directs acoustic energy at selected naturally occurring nucleation features to control motion in the fluid. In another embodiment, the invention provides focused or unfocussed acoustic energy to selectively placed nucleation features to control fluid motion. According to one embodiment, the invention includes an acoustic source, a controller for controlling operation of the acoustic source, and one or more nucleation features located proximate to or in the fluid to be controlled (abstract).

The apparatus includes an acoustic energy source, such as an ultrasound transducer; a controller for providing a waveform type and amplitude controlling signal to the transducer; and one or more nucleation promoting features.

In other embodiments one or both of the acoustic source and the controller are fabricated separately from and located remotely to the microdevice.

In some embodiments, the acoustic source is movable with respect to the target microdevice components.

In certain embodiments, the apparatus includes a source of sonic energy, a sensor for monitoring the energy or its effect, and a feedback mechanism coupled with the source of sonic energy to regulate the energy (for example, voltage, frequency, pattern) for transmitting ultrasonic energy to a target. Devices for transmission may include detection and feedback circuits to control one or more of losses of energy at boundaries and in transit via reflection, dispersion, diffraction, absorption, dephasing and detuning. For example, these devices can control energy according to known loss

patterns, such as beam splitting. Sensors can detect the effects of ultrasonic energy on targets, for example, by measuring electromagnetic emissions, typically in the visible, IR, and UV ranges, optionally as a function of wavelength. These effects include energy dispersion, scattering, absorption, and/or fluorescence emission. Other measurable variables include electrostatic properties such as conductivity, impedance, inductance, and/or the magnetic equivalents of these properties. Measurable parameters also include observation of physical uniformity, pattern analysis, and temporal progression uniformity across an assembly of treatment vessels, such as a microtiter plate.

As shown in FIG. 1, one or more sensors coupled to a feedback control results in more focused, specific, or controlled treatment than that possible using current methods typical in the art. The feedback methodology can include fixed electronic elements, a processor, a computer, and/or a program on a computer (control means). The electronic elements, processor, computer, and/or computer program can in turn control any of a variety of adjustable properties to selectively expose a sample to sonic energy in a given treatment. These properties can include modulation of the ultrasonic beam in response to a detected effect. Modifiable ultrasonic wave variables can include intensity, duty cycle, pulse pattern, and spatial location. Typical input parameters that can trigger an output can include change in level of signal, attainment of critical level, plateauing of effect, and/or rate of change. Typical output actions can include sonic input to sample, such as frequency, intensity, duty cycle; stopping sample movement or sonic energy; and/or moving beam within a sample or to the next sample.

Optical or video detection and analysis can be employed to optimize treatment of the sample. For example, in a suspension of biological tissue, the viscosity of the mixture can increase during treatment due to the diminution of the particles by the treatment and/or by the liberation of macromolecules into the solution. Video analysis of the sample during treatment allows an automated assessment of the mixing caused by the treatment protocol. The protocol may be modified during the treatment to promote greater mixing as a result of this assessment. The video data may be acquired and analyzed by the computer control system that is controlling the treatment process. Other optical measurements such as spectral excitation, absorption, fluorescence, emission, and spectral analysis also can be used to monitor treatment of the sample. A laser beam, for example, can be used for alignment and to indicate current sample position.

Information from the temperature sensor can be used in a feedback loop to control the duty cycle of the acoustic input, such as the number of bursts/second, or otherwise control the amount of heating. Also, fluorescence from an intercalated probe can provide a computer with information on which wells have reached a certain point in the reaction, such as when a particular level of fluorescence is sensed, allowing, for example, the computer to control application of sonic energy or sample location such that certain wells are skipped in the processing cycle until other wells have attained the same point in the reaction or that certain wells are not processed further.

6. Claims 7, 10-11, and 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Akira JP2000338113.

Akira discloses a structurally equivalent chemical analyzer including a pair of side array sound sources 205 and a pair of sound receiving elements 207 respectively opposite to one another are operated to measure the transmission of partial acoustic wave of the reaction vessel 102 at the position. This measurement is executed on each pair, a transmission amount of acoustic wave at each position is measured, and a position of the maximum difference in the transmission amount is regarded as a position of a liquid surface 209. When the acoustic wave of polarized intensity is applied .from a lower sound source 206 to a sound source side, and the liquid surface 209 is pressed up to a reaction vessel 102 side surface, the liquid surface 209 is lowered at a side surface at the opposite side. This is determined by the surface tension, concentration, hydrophilic property to a vessel wall and the like of an object to be stirred, and the characteristics can be identified on the basis of the intensity of the applied acoustic wave and the polarization of the liquid surface 209. This detection is executed not only before the stirring but also similarly executed after the stirring to be compared, and the achievement in stirring and mixing can be evaluated.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Williams; Roger O. et al.; Horine; David A. et al.; Williams; Roger O. et al.; and Sheiman; Vladimir Lvovich disclose devices employing acoustic radiation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/
Primary Examiner
Art Unit 1797